

House File 722 - Reprinted

HOUSE FILE _____
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 226)

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act providing for the creation of an electronic drug database,
2 establishing fees, providing penalties, and providing an
3 effective date.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
5 TLSB 1293HV 81
6 rn/sh/8

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1 1 Section 1. Section 22.7, Code 2005, is amended by adding
1 2 the following new subsection:
1 3 NEW SUBSECTION. 51. The information contained in the
1 4 electronic drug database established in section 124.510A,
1 5 except to the extent that disclosure is authorized pursuant to
1 6 section 124.510C.
1 7 Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG DATABASE
1 8 ESTABLISHED.
1 9 The board shall establish and maintain an electronic drug
1 10 database. The board shall use the electronic drug database to
1 11 monitor the misuse, abuse, and diversion of selected
1 12 controlled substances and other drugs the board includes in
1 13 the database pursuant to section 124.510E, subsection 1,
1 14 paragraph "i". The board shall electronically collect and
1 15 disseminate information pursuant to sections 124.510C and
1 16 124.510D and rules adopted pursuant to this division. The
1 17 board may contract with a third-party/private vendor to
1 18 administer the electronic drug database.
1 19 Sec. 3. NEW SECTION. 124.510B DATA REPORTING.
1 20 1. Each licensed pharmacy that dispenses selected drugs
1 21 identified by the board by rule to patients in the state, and
1 22 each licensed pharmacy located in the state that dispenses
1 23 such selected drugs to patients inside or outside the state,
1 24 unless specifically excepted in this section or by rule, shall
1 25 submit the following prescription information to the board or
1 26 its designee:
1 27 a. Pharmacy identification.
1 28 b. Patient identification.
1 29 c. Prescriber identification.
1 30 d. The date the prescription was issued by the prescriber.
1 31 e. The date the prescription was dispensed.
1 32 f. An indication of whether the prescription dispensed is
1 33 new or a refill.
1 34 g. Identification of the drug dispensed.
1 35 h. Quantity of the drug dispensed.
2 1 i. The number of days' supply of the drug dispensed.
2 2 j. Serial or prescription number assigned by the pharmacy.
2 3 k. Source of payment for the prescription.
2 4 2. Information shall be submitted electronically in the
2 5 format specified by the board unless the board has granted a
2 6 waiver and approved an alternate format.
2 7 3. Information shall be timely transmitted as designated
2 8 by the board by rule, unless the board grants an extension.
2 9 The board may grant an extension if either of the following
2 10 occurs:
2 11 a. The pharmacy suffers a mechanical or electronic
2 12 failure, or cannot meet the deadline established by the board
2 13 for other reasons beyond the pharmacy's control.
2 14 b. The board or its designee is unable to receive
2 15 electronic submissions.
2 16 4. This section shall not apply to a prescriber
2 17 furnishing, dispensing, supplying, or administering drugs to

2 18 the prescriber's patient, or to dispensing by a licensed
2 19 pharmacy for the purposes of inpatient hospital care,
2 20 inpatient hospice care, or long-term residential facility
2 21 patient care.

2 22 Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

2 23 1. The board or its designee may provide information from
2 24 the electronic drug database to all of the following:

2 25 a. A person who is a designated representative of a
2 26 governmental entity responsible for the licensure, regulation,
2 27 or discipline of licensed health care professionals authorized
2 28 to prescribe or dispense drugs, who is involved in an
2 29 investigation of a person licensed, regulated, or subject to
2 30 discipline by the entity, and who is seeking access to
2 31 information in the database that is relevant to the subject
2 32 matter of the investigation and pursuant to a written probable
2 33 cause determination.

2 34 b. A federal, state, county, township, or municipal
2 35 officer of this or any other state, or the United States,
3 1 whose duty it is to enforce the laws relating to prescription
3 2 drugs and who is actively engaged in a specific investigation
3 3 of a specific person and is seeking access to information in
3 4 the database pursuant to a probable cause determination or
3 5 warrant.

3 6 c. A properly convened grand jury pursuant to a subpoena
3 7 properly issued.

3 8 d. A pharmacist or prescriber who requests the information
3 9 and certifies in a form specified by the board that it is for
3 10 the purpose of providing medical or pharmaceutical care to a
3 11 patient of the pharmacist or prescriber.

3 12 e. An individual who requests the individual's own
3 13 database information in accordance with the procedure
3 14 established in rules of the board adopted under section
3 15 124.510E.

3 16 2. The board or its designee shall maintain a record of
3 17 each person that requests information from the database.
3 18 Pursuant to rules adopted by the board under section 124.510E,
3 19 the board may use the records to document and report
3 20 statistics and law enforcement outcomes and to identify
3 21 inappropriate access or other prohibited acts. The board or
3 22 its designee may provide records of a person's requests for
3 23 database information to the following persons:

3 24 a. Pursuant to a probable cause determination, a
3 25 designated representative of a governmental entity that is
3 26 responsible for the licensure, regulation, or discipline of
3 27 licensed health care professionals authorized to prescribe or
3 28 dispense drugs who is involved in a specific investigation of
3 29 the individual who submitted the request.

3 30 b. Pursuant to a probable cause determination or warrant,
3 31 a federal, state, county, township, or municipal officer of
3 32 this or any other state or the United States, whose duty is to
3 33 enforce the laws relating to prescription drugs, and who is
3 34 actively engaged in a specific investigation of the specific
3 35 person who submitted the request.

4 1 3. Information contained in the database and any
4 2 information obtained from it is strictly confidential medical
4 3 information, is not a public record pursuant to chapter 22,
4 4 and is not subject to discovery, subpoena, or other means of
4 5 legal compulsion for release except as provided in this
4 6 division. Information contained in the records of requests
4 7 for information from the database is privileged and
4 8 confidential, is not a public record, and is not subject to
4 9 discovery, subpoena, or other means of legal compulsion for
4 10 release except as provided in this division. Information from
4 11 the database shall not be released, shared with an agency or
4 12 institution, or made public except as provided in this
4 13 division.

4 14 4. Information collected for the database shall be
4 15 retained in the database for four years. The information
4 16 shall then be destroyed unless a law enforcement agency or a
4 17 governmental entity responsible for the licensure, regulation,
4 18 or discipline of licensed health care professionals authorized
4 19 to prescribe or dispense drugs has submitted a written request
4 20 to the board or its designee for retention of specific
4 21 information in accordance with rules adopted by the board
4 22 under section 124.510E.

4 23 5. A pharmacist or other dispenser making a report to the
4 24 database in good faith pursuant to this division is immune
4 25 from any liability, civil, criminal, or administrative, which
4 26 might otherwise be incurred or imposed as a result of the
4 27 report.

4 28 6. Nothing in this section shall require a pharmacist or

4 29 prescriber to obtain information about a patient from the
4 30 database. A pharmacist or prescriber does not have a duty and
4 31 shall not be held liable in damages to any person in any civil
4 32 or derivative criminal or administrative action for injury,
4 33 death, or loss to person or property on the basis that the
4 34 pharmacist or prescriber did or did not seek or obtain
4 35 information from the database. A pharmacist or prescriber
5 1 acting in good faith is immune from any civil, criminal, or
5 2 administrative liability that might otherwise be incurred or
5 3 imposed for requesting or receiving information from the
5 4 database.

5 5 7. The board shall not charge a fee to a pharmacy,
5 6 pharmacist, or prescriber for the establishment, maintenance,
5 7 or administration of the database. The board shall not charge
5 8 a fee for the transmission of data to the database nor for the
5 9 receipt of information from the database, except that the
5 10 board may charge a reasonable fee to an individual who
5 11 requests the individual's own database information or to a
5 12 person requesting statistical, aggregate, or nonpersonally
5 13 identified information from the database. A fee charged
5 14 pursuant to this subsection shall not exceed the cost of
5 15 providing the requested information and shall be considered a
5 16 repayment receipt as defined in section 8.2.

5 17 Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND REFERRAL.

5 18 The board or its designee shall review the information in
5 19 the electronic drug database. If the board determines,
5 20 consistent with the board's authority under this chapter or
5 21 chapter 155A, that there is probable cause to believe that
5 22 drug diversion or another violation of law may have occurred,
5 23 the board shall notify the appropriate law enforcement agency
5 24 or the governmental entity responsible for the licensure,
5 25 regulation, or discipline of the licensed health care
5 26 professional, and shall supply information required to
5 27 initiate an investigation. The board shall not refer
5 28 information relating to an individual for further
5 29 investigation except upon a probable cause determination. A
5 30 probable cause determination shall be consistent with
5 31 guidelines developed by the advisory council established under
5 32 section 124.510F.

5 33 Sec. 6. NEW SECTION. 124.510E RULES AND REPORTING.

5 34 1. The board shall adopt rules in accordance with chapter
5 35 17A to carry out the purposes of, and to enforce the
6 1 provisions of, this division. The rules shall include but not
6 2 be limited to the development of procedures relating to:

6 3 a. Identifying each patient about whom information is
6 4 entered into the electronic drug database.

6 5 b. An electronic format for the submission of information
6 6 from pharmacies.

6 7 c. A waiver to submit information in another format for a
6 8 pharmacy unable to submit information electronically.

6 9 d. Granting by the board of a request from a law
6 10 enforcement agency or a governmental entity responsible for
6 11 the licensure, regulation, or discipline of licensed health
6 12 care professionals authorized to prescribe or dispense drugs
6 13 for the retention of information scheduled for deletion from
6 14 the database after four years when the information pertains to
6 15 an open investigation being conducted by the agency or entity.

6 16 e. An application for an extension of time by a pharmacy
6 17 regarding information to be transmitted to the board or its
6 18 designee.

6 19 f. The submission by a person or governmental entity to
6 20 which the board is authorized to provide information of a
6 21 request for the information and a procedure for the
6 22 verification of the identity of the requestor.

6 23 g. Use by the board of the database request records
6 24 required by section 124.510C, subsection 2, to document and
6 25 report statistics and law enforcement outcomes and to identify
6 26 inappropriate access or other prohibited acts.

6 27 h. Submission of a request by an individual for the
6 28 individual's own database information and verification of the
6 29 identity of the requestor.

6 30 i. The development of a list of controlled substances and
6 31 other drugs that shall be included in the database.

6 32 j. Access by a pharmacist or prescriber to information in
6 33 the database pursuant to a written agreement with the board.

6 34 k. Terms and conditions of the contract, if the board
6 35 contracts for database administration with a third-party or
7 1 private vendor.

7 2 1. The correction or deletion of erroneous information
7 3 from the database.

7 4 2. No later than January 1, 2008, and every two years

7 5 thereafter, the board shall present to the general assembly
7 6 and the governor a report of the following:
7 7 a. The cost to the state of implementing and maintaining
7 8 the database.
7 9 b. Information from pharmacies, prescribers, the board,
7 10 and others regarding the usefulness of the database.
7 11 c. Information from pharmacies, prescribers, the board,
7 12 and others regarding the board's effectiveness in providing
7 13 information from the database.
7 14 d. Information documenting the timely transmission of
7 15 information from the electronic drug database to authorized
7 16 requestors.

7 17 Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL
7 18 ESTABLISHED.

7 19 The board shall establish an advisory council to provide
7 20 oversight to the electronic drug database program. The board
7 21 shall adopt rules specifying the duties and activities of the
7 22 advisory council and related matters.

7 23 1. The council shall consist of three licensed
7 24 pharmacists, three licensed physicians, two licensed
7 25 prescribers who are not physicians, and two members of the
7 26 general public. The board shall solicit recommendations for
7 27 health professional council members from Iowa health
7 28 professional licensing boards, associations, and societies.
7 29 The license of each health professional appointed to and
7 30 serving on the advisory council shall be current and in good
7 31 standing with the professional's licensing board.

7 32 2. The council may make recommendations to advance the
7 33 goals of the database, which include identification of misuse
7 34 and diversion of identified controlled substances and other
7 35 drugs and enhancement of the quality of health care delivery
8 1 in this state.

8 2 3. Among other things, the council shall:

8 3 a. Assist the board in developing criteria for granting
8 4 requests by researchers and other persons for statistical,
8 5 aggregate, or nonpersonally identified information using
8 6 database information, developed consistent with the goals of
8 7 the database.

8 8 b. Assist the board in ensuring patient confidentiality
8 9 and the integrity of the patient's treatment relationship with
8 10 the patient's health care provider.

8 11 c. Make recommendations regarding the continued benefits
8 12 of maintaining the electronic drug database in relationship to
8 13 cost and other burdens to the board. The council's
8 14 recommendations shall be included in reports required by
8 15 section 124.510E, subsection 2.

8 16 3. Members of the advisory council shall be eligible to
8 17 request and receive actual expenses for their duties as
8 18 members of the advisory council, subject to reimbursement
8 19 limits imposed by the department of administrative services,
8 20 and shall also be eligible to receive a per diem compensation
8 21 as provided in section 7E.6, subsection 1.

8 22 Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS AND
8 23 PENALTIES.

8 24 The failure of a licensed pharmacist or licensed prescriber
8 25 to comply with the requirements of this division, or the
8 26 performance or causing the performance of, or the aiding and
8 27 abetting of another person in the performance of, any of the
8 28 prohibited acts identified in this section shall constitute
8 29 grounds for disciplinary action against the pharmacist or
8 30 prescriber by the appropriate professional licensing board.
8 31 Each licensing board that licenses prescribers and drug
8 32 dispensers subject to the provisions of this division may
8 33 adopt rules in accordance with chapter 17A to implement the
8 34 provisions of this section and may impose penalty as allowed
8 35 under section 272C.3. In addition, a civil penalty not to
9 1 exceed twenty-five thousand dollars for each violation may be
9 2 imposed.

9 3 1. A pharmacist who willfully and knowingly fails to
9 4 submit prescription information to the board or its designee
9 5 as required by this division, or who knowingly and
9 6 intentionally submits prescription information known to the
9 7 pharmacist to be false or fraudulent, may be subject to
9 8 disciplinary action by the board.

9 9 2. A person authorized to access or receive prescription
9 10 information pursuant to this division who willfully and
9 11 knowingly discloses or attempts to disclose such information
9 12 with the intent to cause harm to another person in violation
9 13 of this division is guilty of a class "D" felony.

9 14 3. A person who willfully and knowingly uses, releases,
9 15 publishes, or otherwise makes available to another person any

9 16 personally identifiable information obtained from or contained
9 17 in the database is guilty of a serious misdemeanor.

9 18 4. A person without lawful authority who obtains or
9 19 attempts to obtain information, obtains or attempts to obtain
9 20 unauthorized access to, or who willfully and knowingly alters
9 21 or destroys valid information contained in the database is
9 22 guilty of a class "D" felony.

9 23 5. A person authorized to access or receive prescription
9 24 information pursuant to this division who knowingly and
9 25 intentionally discloses confidential information to a person
9 26 who is not authorized to receive the information pursuant to
9 27 this division is guilty of a serious misdemeanor.

9 28 6. This section shall not preclude a pharmacist or
9 29 prescriber who requests and receives information from the
9 30 database consistent with the requirements of this chapter from
9 31 otherwise lawfully providing that information to any other
9 32 person for medical or pharmaceutical care purposes.

9 33 Sec. 9. EFFECTIVE DATE. This Act, being deemed of
9 34 immediate importance, takes effect upon enactment.

9 35 HF 722

10 1 rn:nh/es/25